

## PACKAGE INSERT LEAFLET: INFORMATION FOR THE USER

### MOTILIUM

#### **10 mg film-coated tablets**

*(12,72 mg of domperidone maleate = 10 mg of domperidone per tablet)*

#### **10 mg film-coated tablets**

*(10 mg of domperidone per tablet)*

#### **Instant 10 mg orodispersible tablets**

*(10 mg of domperidone per tablet)*

#### **Read all of this leaflet carefully before you start taking this medicine.**

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- If you get any side effects not mentioned in section 4, including any possible side effects not listed in this leaflet, check with your doctor or pharmacist.

#### **What is in this leaflet:**

1. What Motilium is and what it is used for
2. Warnings and precautions
3. Taking this medicine
4. Possible side effects
5. How to store this medicine
6. Contents of the pack and other information

### **1. WHAT MOTILIUM IS AND WHAT IS IT USED FOR**

Motilium 10 mg film-coated tablets or orodispersible tablets are used to treat nausea and vomiting in adults and adolescents (from 12 years of age and with a body weight of 35 kg or more).

### **2. WARNINGS AND PRECAUTIONS**

#### **Do not take this medicine:**

- If you have an allergy to one of the ingredients of this medicine. These ingredients are listed in section 6.
- If you have a stomach bleeding or regularly have serious abdominal pain or persistent black stools;
- If you have a blocked or perforated intestine;
- If you have a tumour of the hypophysis (prolactinoma);
- If you have a disorder known as phenylketonuria (a metabolic disorder). Orodispersible tablets must not be used because they contain aspartame;
- If you have a moderate or serious liver disease;
- Your ECG (electrocardiogram or echogram for the heart) indicates that you have a heart problem called “corrected QT interval prolongation”;
- If you have or had a problem causing your heart to be unable to pump enough blood through your body (a condition called heart failure);
- If you have a problem causing low potassium or magnesium levels or high potassium levels in the blood;
- If you use certain medicines (“Other medicines and Motilium?”).

## **When to take special care with Motilium**

Talk to your doctor before taking this medicine if you:

- have liver problems (liver function disorders or liver failure) (see “Warnings and precautions”);
- have kidney problems (kidney function disorders or kidney failure). Ask your doctor for advice in case of long-term treatment, because you will probably have to use a lower dose or use this medicine less often. Your doctor may also consider a regular examination necessary.

Domperidone may be associated with a higher risk of cardiac arrhythmias and cardiac arrest. Chances of this are greater in people over 60 years of age or in people taking a dose higher than 30 mg per day. Chances of this are also greater if domperidone is used together with certain other medicines. Tell your doctor or pharmacist if you use medicines against infections (fungal infections or bacterial infections) and/or if you have heart problems or AIDS/HIV (see the section “Other medicines and Motilium?”).

The lowest effective dose of Motilium must be used.

Contact your doctor if you experience cardiac arrhythmias such as palpitations, breathing difficulties or loss of consciousness when using Motilium. The treatment with Motilium must be discontinued.

### **Adolescents weighing less than 35 kg and children**

Motilium should not be given to adolescents 12 years of age and older weighing less than 35 kg, or in any children less than 12 years of age, as it is not effective in these age groups.

### **Other medicines and Motilium**

Do you use other medicines in addition to Motilium or did you do so a short time ago or is there a possibility that you will use other medicines in the near future? Tell your doctor or pharmacist.

Do not use Motilium if you use medicines to treat:

- fungal infections, such as pentamidine or azole antifungal medication, especially itraconazole, oral ketoconazole, fluconazole, posaconazole or voriconazole;
- bacterial infections, particularly erythromycin, clarithromycin, telithromycin, levofloxacin, moxifloxacin, spiramycin (these are antibiotics);
- heart problems or high blood pressure (e.g. amiodarone, dronedarone, ibutilide, kinidine, disopyramide, dofetilide, sotalol, hydrokinidine);
- psychosis (e.g. haloperidol, pimozide, sertindol);
- depression (e.g. citalopram, escitalopram);
- gastrointestinal disorders (e.g. cisapride, dolasetron, prucalopride);
- allergy (e.g. mequitazine, mizolastine);
- malaria (particularly halofantrine, lumefantrine);
- AIDS/HIV such as e.g. ritonavir or saquinavir (these are protease inhibitors);
- hepatitis C (e.g. telaprevir);
- cancer (e.g. toremifene, vandetanib, vincamine).

No not take Motilium if you use certain other medicines (e.g. bepridil, difemanil, methadone).

Tell your doctor or pharmacist if you use medicines against infections, heart problems, AIDS/HIV or Parkinson's disease.

### **Motilium and apomorphine**

Before you use Motilium and apomorphine, your doctor will check if you tolerate both medicines in case of concomitant use. Ask your doctor or specialist for personal advice. Consult the package insert leaflet of apomorphine.

It is important to ask your doctor or pharmacist if Motilium is safe for you if you use other medicines, including OTC medicines.

### **Motilium with food and drink**

It is recommended to take Motilium before meals. If it is taken after the meal the absorption of the medicine is somewhat delayed.

### **Pregnancy**

It is not known if the use of Motilium is harmful during pregnancy.

If you are pregnant, think you may be pregnant, want to become pregnant or are breastfeeding, then talk to your doctor or pharmacist before taking this medicine. Your doctor will decide whether you should use this medicine.

### **Breast feeding**

Small amounts of Motilium have been found in breast milk. Motilium may cause adverse reactions which influence the heart of a breast-fed baby. Motilium must be used during breastfeeding only if your doctor considers it strictly necessary. Ask your doctor for advice before you take this medicine.

### **Driving and using machines**

Some patients have reported dizziness or drowsiness after taking Motilium. Do not drive vehicles while taking Motilium until you know how it affects you.

### **What Motilium contains**

- The orodispersible tablets contain aspartame and should therefore not be used by patients suffering from phenylketonuria.
- The film-coated tablets contain lactose (a kind of sugar). If you have been told by your doctor that you have an intolerance to some sugars, talk to your doctor before using this product.

## **3. TAKING THIS MEDICINE**

Follow these instructions carefully, unless your doctor prescribes you otherwise. You should check with your doctor or pharmacist if you are not sure.

It is recommended to take Motilium before meals. If it is taken after the meal the absorption of the medicine is somewhat delayed.

### **Duration of treatment**

The symptoms usually disappear within 3-4 days after you start using this medicine. Do not use Motilium for more than 7 days without talking to your doctor.

### **Adults and young people from 12 years of age and with a body weight of 35 kg or more**

#### Tablets 10 mg:

The recommended dose is one tablet, maximum three times per day, if possible before meals. Do not take more than three tablets per day. Take the tablets with some water or another liquid. Do not chew the tablets.

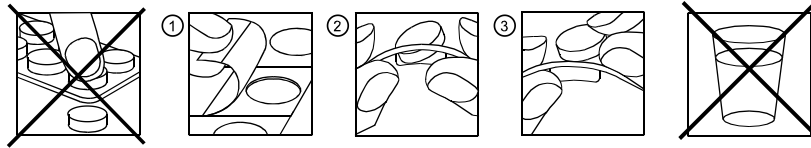
#### Orodispersible tablets 10 mg:

The recommended dose is one tablet, maximum three times per day, if possible before meals. Do not take more than three tablets per day.

The orodispersible tablets are fragile, which means that they should not be pushed through the foil as they would get broken or damaged.

Remove the tablet from the blister pack as follows:

- Do not push the tablet through the foil.
- Pull the foil up by the edge and remove it completely (Figure 1).
- Push the tablet upwards (Figure 2).
- Remove the tablet from the blister (Figure 3).
- Put the orodispersible tablet on the tongue. It will melt automatically and is ingested with saliva. There is no need to drink.



#### **If you take more Motilium than you should**

If you have taken more Motilium than you should, immediately contact your doctor, pharmacist or the Poison Control Centre (070/245.245). In case of an overdose a symptomatic treatment may be initiated. Because of the chance of a heart problem called QT interval prolongation, an ECG check may be performed.

Information for the doctor: careful observation of the patient and general supporting measures are recommended. Anticholinergic anti-Parkinson's medicines may help to fight the extrapyramidal disorders.

#### **If you forget to take this medicinal product**

Take the medicinal product as soon as you remember. However, if it is nearly time for the following dose, then skip the forgotten dose and continue the normal scheme. Do not take a double dose to make up for a forgotten dose.

## **4. POSSIBLE SIDE EFFECTS**

Like all medicines, this medicine can cause side effects, although not everybody gets them.

**Uncommon** (reported by less than 1 in 100 patients):

- Involuntary movements of the face, arms or legs, excessive trembling, excessive muscle rigidity or muscle spasms.

**Not known** (cannot be determined with the available data):

- Convulsions;
- A kind of reaction which may occur soon after administration and which can be recognized by rash, itching, shortness of breath, and/or a swollen face;
- A serious hypersensitivity reaction which may occur soon after administration and can be recognized by hives, itching, hot flushes, fainting, breathing difficulties, and other possible symptoms;
- Disorders of the heart and the blood vessels (the cardiovascular system): cardiac arrhythmias (fast or irregular heartbeat) have been reported. Should this occur, the treatment must be stopped immediately. Domperidone may be associated with a higher risk of cardiac arrhythmias and cardiac arrest. Chances of this may be greater in people over 60 years of age or in people taking a dose higher than 30 mg per day. The lowest effective dose of domperidone must be used.

**Stop the Motilium treatment and immediately contact your doctor** if you notice the adverse reactions described above.

Other adverse reactions observed with Motilium are listed below:

**Common** (reported by at least 1 in 100 patients but by less than 1 in 10 patients):

- Dry mouth.

**Uncommon** (reported by at least 1 in 1000 patients but by less than 1 in 100 patients):

- Anxiety;
- Restlessness;
- Nervousness;
- Loss of libido or decreased interest in sex;
- Headache;
- Drowsiness;
- Diarrhoea;
- Rash;
- Itching;
- Hives;
- Painful or sensitive breasts;
- Lactation from the breasts;
- General feeling of weakness;
- Feeling dizzy.

**Not known** (cannot be determined with the available data):

- Eyes turning upwards;
- No menstruation in women;
- Enlarged breasts in men;
- Inability to urinate;
- Changes in certain laboratory test results;
- “Restless leg” syndrome (discomfort, with an irresistible urge to move the legs, and sometimes the arms and other body parts).

Some patients who have used Motilium for disorders and in doses which require medical supervision experienced the following adverse reactions: restlessness, swollen or enlarged breasts, unusual secretion from the breasts, irregular menstruation in women, breastfeeding difficulties, depression, oversensitivity.

### **Reporting of side effects**

If you experience side effects, contact your doctor or pharmacist. By reporting side effects, you can help us to obtain more information on the safety of a medicine.

## **5. HOW TO STORE THIS MEDICINE**

- Keep out of sight and reach of children.
- Do not use this medicine after the longest expiry date. This is stated on the pack after the letters „EXP“. This mentions a month and a year. The last day of that month is the final expiry date.
- Store between 15 and 30 °C , protect from light .

Do not flush medicines down the sink or the WC and do not throw them out in the dustbin. Ask your pharmacist what to do with medicines that you are no longer using. They are then destroyed in a responsible way and do not enter the environment.

## **6. CONTENTS OF THE PACK AND OTHER INFORMATION**

### **What Motilium contains**

- The active substance is domperidone.
- The other ingredients are:  
Film-coated tablets (domperidone maleate): lactose, maize starch, microcrystalline cellulose, polyvidon, potato starch, magnesium stearate, silicon dioxide, polysorbate 20, hydroxypropyl methyl cellulose, propylene glycol.  
Film-coated tablets (domperidone): lactose, maize starch, microcrystalline cellulose, potato starch, polyvidon, magnesium stearate, vegetable oil, sodium lauryl sulphate, hypromellose.  
Orodispersible tablets: gelatine, mannitol (E421), aspartame (E951), mint flavour, poloxamer 188.

**What Motilium looks like and contents of the pack**

- The film-coated tablets (domperidone maleate) are available in a blister pack containing 30 or 100 tablets.
- The film-coated tablets (domperidone) are available in a blister pack containing 30 or 100 tablets.
- The orodispersible tablets are available in a blister pack containing 10, 20 or 30 tablets.

Not all pack sizes may be marketed.

**Marketing authorisation holder:**

Janssen-Cilag NV Antwerpseweg 15-17 -B-2340 Beerse, Belgium

**Manufacturer:**

Iusomedicamenta-sociedadee Tecnica Farmaceutica,SA Estrada consiglieri pedroso 69B- Quelez de Baixo 2730-055 Barcarena- portugal.

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To contact us, go to [www.janssen.com/contact-us](http://www.janssen.com/contact-us)

**This package insert was last approved in 15 March 2019**

**THIS IS A MEDICAMENT**

- Medicament is a product which affects your health and its consumption contrary to instructions is dangerous for you.
- Follow strictly the doctor's prescription, the method of use and the instructions of the pharmacist who sold the medicament. The doctor and the pharmacist are the experts in medicines, their benefits and risks.
- Do not by yourself interrupt the period of treatment prescribed.
- Do not repeat the same prescription without consulting your doctor.
- Keep all medicaments out of the reach of children

**Council of Arab Health Ministers, Union of Arab Pharmacists**